



March 10, 2023

Scientia Vascular, Inc.  
Thomas Lippert  
Regulatory Affairs Associate  
3487 West 2100 South Suite 100  
West Valley City, Utah 84119

Re: K220398

Trade/Device Name: Aristotle 14 Guidewire; Aristotle 18 Guidewire; Aristotle 24 Guidewire; Volo 14 Guidewire; Zoom Wire 14 Guidewire

Regulation Number: 21 CFR 870.1330

Regulation Name: Catheter Guide Wire

Regulatory Class: Class II

Product Code: MOF, DQX,

Dated: February 10, 2023

Received: February 10, 2023

Dear Thomas Lippert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

  
Naira Muradyan -S

Naira Muradyan, Ph.D.

Assistant Director

DHT5A: Division of Neurosurgical,  
Neurointerventional  
and Neurodiagnostic Devices

OHT5: Office of Neurological  
and Physical Medicine Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K220398

Device Name

Aristotle 14 Guidewire; Aristotle 18 Guidewire; Aristotle 24 Guidewire; Volo 14 Guidewire; Zoom Wire 14 Guidewire

Indications for Use (Describe)

The Aristotle 14 Guidewire is intended for general vascular use within the neuro and peripheral vasculatures to introduce and position catheters and other interventional devices. The guidewire is not intended for use in the coronary vasculature.

The Aristotle 18 Guidewire is intended for general vascular use within the neuro and peripheral vasculatures to introduce and position catheters and other interventional devices. The guidewire is not intended for use in the coronary vasculature.

The Aristotle 24 Guidewire is intended for general vascular use within the neuro and peripheral vasculatures to introduce and position catheters and other interventional devices. The guidewire is not intended for use in the coronary vasculature.

The Volo 14 Guidewire is intended for general vascular use within the neuro and peripheral vasculatures to introduce and position catheters and other interventional devices. The guidewire is not intended for use in the coronary vasculature.

The Zoom Wire 14 Guidewire is intended for general vascular use within the neuro and peripheral vasculatures to introduce and position catheters and other interventional devices. The guidewire is not intended for use in the coronary vasculature.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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## **K220398 510(k) SUMMARY**

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Date Prepared: March 9, 2023

**Table 1. Subject Device Information**

<b>Aristotle 14 Guidewire</b>	
Trade Name:	Aristotle 14 Guidewire
Common Name:	Guidewire
Classification Name	Catheter Guide Wire per 21 CFR 870.1330
Primary Product Code:	MOF
Subsequent Product Code	DQX
Predicate Device:	Aristotle 14 Guidewire (K173235)
<b>Aristotle 18 Guidewire</b>	
Trade Name:	Aristotle 18 Guidewire
Common Name:	Guidewire
Classification Name	Catheter Guide Wire per 21 CFR 870.1330
Primary Product Code:	MOF
Subsequent Product Code	DQX
Predicate Device:	Aristotle 18 Guidewire (K183608)
<b>Aristotle 24 Guidewire</b>	
Trade Name:	Aristotle 24 Guidewire
Common Name:	Guidewire
Classification Name	Catheter Guide Wire per 21 CFR 870.1330
Primary Product Code:	MOF
Secondary Product Code	DQX
Predicate Device:	Aristotle 24 Guidewire (K192783)
<b>Volo 14 Guidewire</b>	
Trade Name:	Volo 14 Guidewire
Common Name:	Guidewire
Classification Name	Catheter Guide Wire per 21 CFR 870.1330
Primary Product Code:	MOF
Subsequent Product Code	DQX
Predicate Device:	Volo 14 Guidewire (K181828)
<b>Zoom Wire 14 Guidewire</b>	
Trade Name:	Zoom Wire 14 Guidewire
Common Name:	Guidewire
Classification Name	Catheter Guide Wire per 21 CFR 870.1330
Primary Product Code:	MOF
Subsequent Product Code	DQX
Predicate Device:	Zoom 14 Guidewire (K201760)

## **DEVICE DESCRIPTION**

The Scientia Vascular's Aristotle 14, Aristotle 18, Aristotle 24, Volo 14, and Zoom Wire 14 Guidewires ("the guidewires") are steerable guidewires with a shapeable tip to aid in accessing the neuro and peripheral vasculatures. The guidewires are supplied sterile, for single use only, in the following diameters, stiffness profiles, and lengths:

Aristotle 14 Guidewire	
Diameter	0.014"
Stiffness Profiles	Soft, Standard
Lengths	200 cm, 300 cm

  

Aristotle 18 Guidewire	
Diameter	0.018"
Stiffness Profiles	Soft, Standard, Support
Length	200 cm

  

Aristotle 24 Guidewire	
Diameter	0.024"
Stiffness Profiles	Soft, Standard, Support
Length	200 cm

  

Volo 14 Guidewire	
Diameter	0.014"
Stiffness Profiles	Soft, Standard
Lengths	200 cm, 300 cm

  

Zoom Wire 14 Guidewire	
Diameter	0.014"
Stiffness Profiles	Support, Extra Support
Lengths	200 cm, 300 cm

The distal portion of each guidewire's tip includes a radiopaque platinum wire marker coil to facilitate fluoroscopic visualization. All guidewires have a hydrophilic polymer coating on the distal portion and a polytetrafluoroethylene (PTFE) coating on the proximal portion to reduce friction during manipulation in vessels.

The guidewires are provided with an accessory kit consisting of an introducer (to aid with the insertion of the guidewire into a catheter hub and/or a hemostasis valve), a torque device (to attach to the proximal portion of the guidewire to facilitate gripping and manipulation of the guidewire during use), and a shaping mandrel (to aid in shaping the flexible tip of the guidewire). These accessory devices are included to facilitate use of the guidewires and are not intended to contact the patient's body.

## **INDICATIONS FOR USE**

### **Aristotle 14 Guidewire**

The Aristotle 14 Guidewire is intended for general vascular use within the neuro and peripheral vasculatures to introduce and position catheters and other interventional devices. The guidewire is not intended for use in the coronary vasculature.

### **Aristotle 18 Guidewire**

The Aristotle 18 Guidewire is intended for general vascular use within the neuro and peripheral vasculatures to introduce and position catheters and other interventional devices. The guidewire is not intended for use in the coronary vasculature.

### **Aristotle 24 Guidewire**

The Aristotle 24 Guidewire is intended for general vascular use within the neuro and peripheral vasculatures to introduce and position catheters and other interventional devices. The guidewire is not intended for use in the coronary vasculature.

### **Volo 14 Guidewire**

The Volo 14 Guidewire is intended for general vascular use within the neuro and peripheral vasculatures to introduce and position catheters and other interventional devices. The guidewire is not intended for use in the coronary vasculature.

### **Zoom Wire 14 Guidewire**

The Zoom Wire 14 Guidewire is intended for general vascular use within the neuro and peripheral vasculatures to introduce and position catheters and other interventional devices. The guidewire is not intended for use in the coronary vasculature.

**INTENDED USE**

The guidewires are intended for use by a physician to help introduce and position catheters or other interventional devices within the neuro and peripheral vasculature.

**COMPARISON OF TECHNOLOGICAL CHARACTERISTICS**

The subject devices have the following similarities to the previously cleared predicate devices:

- The same indications for use,
- The same intended use,
- The same operating principle,
- The same basic guidewire design,
- The similar materials, and
- The same packaging materials and sterilization processes.

The tables (**Table 2 - Table 6**) below provide additional details on the technological characteristics of the subject devices compared to their respective predicate devices.

**Table 2. Aristotle 14 Guidewire Technological Characteristics Comparison**

<b>Characteristic</b>	<b>Subject Device Aristotle 14 Guidewire (K220398)</b>	<b>Predicate Aristotle 14 Guidewire (K173235)</b>	<b>Comparison</b>
<b>Anatomical Location</b>	Neuro and peripheral vasculature	Neuro and peripheral vasculature	Same
<b>Dimensions</b>	<i>O.D.:</i> 0.014" (0.36 mm) <i>Length:</i> 200 cm, 300 cm	<i>O.D.:</i> 0.014" (0.36 mm) <i>Length:</i> 200 cm, 300 cm range	Same
<b>Core Wire</b>	Stainless Steel	Stainless Steel	Same
<b>Distal Tip</b>	Shapeable <i>Length:</i> 35 cm <i>Material:</i> Nitinol	Shapeable <i>Length:</i> 35 cm <i>Material:</i> Nitinol	Same
<b>Stiffness Profiles</b>	Soft, standard	Soft, standard	Same
<b>Coatings</b>	<i>Distal End:</i> Hydrophilic	<i>Distal End:</i> Hydrophilic	Same
	<i>Proximal End:</i> Proposed PTFE	<i>Proximal End:</i> Current PTFE	Different

<b>Characteristic</b>	<b>Subject Device Aristotle 14 Guidewire (K220398)</b>	<b>Predicate Aristotle 14 Guidewire (K173235)</b>	<b>Comparison</b>
<b>Radiopaque Marker</b>	1 radiopaque marker at distal tip	1 radiopaque marker at distal tip	Same
<b>Centering Coil</b>	1 centering coil	1 centering coil	Same
<b>Shaping Mandrel (Accessory)</b>	Provided with each guidewire	NA	Different
<b>Guidewire Introducer (Accessory)</b>	Provided with each guidewire	Provided with each guidewire	Same
<b>Torque Device (Accessory)</b>	Provided with each guidewire	Provided with each guidewire	Same
<b>Sterilization Method</b>	100% Ethylene Oxide (EO)	100% EO	Same
<b>Shelf Life</b>	4 month	3 year	Different

**Table 3. Aristotle 18 Guidewire Technological Characteristics Comparison**

<b>Characteristic</b>	<b>Subject Device Aristotle 18 Guidewire (K220398)</b>	<b>Predicate Aristotle 18 Guidewire (K183608)</b>	<b>Comparison</b>
<b>Anatomical Location</b>	Neuro and peripheral vasculature	Neuro and peripheral vasculature	Same
<b>Dimensions</b>	<b>O.D.:</b> 0.018" (0.46 mm) <b>Length:</b> 200 cm	<b>O.D.:</b> 0.018" (0.46 mm) <b>Length:</b> 200 cm	Same
<b>Core Wire</b>	Stainless Steel	Stainless Steel	Same
<b>Distal Tip</b>	Shapeable <b>Length:</b> 35 cm <b>Material:</b> Nitinol	Shapeable <b>Length:</b> 35 cm <b>Material:</b> Nitinol	Same
<b>Stiffness Profiles</b>	Support, standard, soft	Support, standard, soft	Same
<b>Coatings</b>	<b>Distal End:</b> Hydrophilic	<b>Distal End:</b> Hydrophilic	Same
	<b>Proximal End:</b> Proposed PTFE	<b>Proximal End:</b> Current PTFE	Different

Characteristic	Subject Device Aristotle 18 Guidewire (K220398)	Predicate Aristotle 18 Guidewire (K183608)	Comparison
<b>Radiopaque Marker</b>	1 radiopaque marker at distal tip	1 radiopaque marker at distal tip	Same
<b>Centering Coil</b>	1 centering coil	1 centering coil	Same
<b>Shaping Mandrel (Accessory)</b>	Provided with each guidewire	NA	Different
<b>Guidewire Introducer (Accessory)</b>	Provided with each guidewire	Provided with each guidewire	Same
<b>Torque Device (Accessory)</b>	Provided with each guidewire	Provided with each guidewire	Same
<b>Sterilization Method</b>	100% EO	100% EO	Same
<b>Shelf Life</b>	4 month	3 year	Different

**Table 4. Aristotle 24 Guidewire Technological Characteristics Comparison**

Characteristic	Subject Device Aristotle 24 Guidewire (K220398)	Predicate Aristotle 24 Guidewire (K192783)	Comparison
<b>Anatomical Location</b>	Neuro and peripheral vasculature	Neuro and peripheral vasculature	Same
<b>Dimensions</b>	<b>O.D.:</b> 0.024" (0.61 mm) <b>Length:</b> 200 cm	<b>O.D.:</b> 0.024" (0.61 mm) <b>Length:</b> 200 cm	Same
<b>Core Wire</b>	Stainless steel	Stainless steel	Same
<b>Distal Tip</b>	Shapeable <b>Length:</b> 35 cm <b>Material:</b> Nitinol	Shapeable <b>Length:</b> 35 cm <b>Material:</b> Nitinol	Same
<b>Stiffness Profiles</b>	Support, standard, soft	Support, standard, soft	Same
<b>Coatings</b>	<b>Distal End:</b> Hydrophilic	<b>Distal End:</b> Hydrophilic	Same
	<b>Proximal End:</b> Proposed PTFE	<b>Proximal End:</b> Current PTFE	Different

Characteristic	Subject Device Aristotle 24 Guidewire (K220398)	Predicate Aristotle 24 Guidewire (K192783)	Comparison
<b>Radiopaque Marker</b>	1 radiopaque marker at distal tip	1 radiopaque marker at distal tip	Same
<b>Centering Coil</b>	2 centering coils	2 centering coils	Same
<b>Bushing</b>	1 bushing	1 bushing	Same
<b>Shaping Mandrel (Accessory)</b>	Provided with each guidewire	Provided with each guidewire	Same
<b>Guidewire Introducer (Accessory)</b>	Provided with each guidewire	Provided with each guidewire	Same
<b>Torque Device (Accessory)</b>	Provided with each guidewire	Provided with each guidewire	Same
<b>Sterilization Method</b>	100% EO	100% EO	Same
<b>Shelf Life</b>	4 month	3 year	Different

**Table 5. Volo 14 Guidewire Technological Characteristics Comparison**

Characteristic	Subject Device Volo 14 Guidewire (K220398)	Predicate Volo 14 Guidewire (K181828)	Comparison
<b>Anatomical Location</b>	Neuro and peripheral vasculature	Neuro and peripheral vasculature	Same
<b>Dimensions</b>	<b>O.D.:</b> 0.014" (0.36 mm) <b>Length:</b> 200 cm, 300 cm	<b>O.D.:</b> 0.014" (0.36 mm) <b>Length:</b> 200 cm, 300 cm	Same
<b>Core Wire</b>	Stainless Steel	Stainless Steel	Same
<b>Distal Tip</b>	Shapeable <b>Length:</b> 35 cm <b>Material:</b> Nitinol	Shapeable <b>Length:</b> 35 cm <b>Material:</b> Nitinol	Same
<b>Stiffness Profiles</b>	Soft, standard	Soft, standard	Same
<b>Coatings</b>	<b>Distal End:</b> Hydrophilic	<b>Distal End:</b> Hydrophilic	Same
	<b>Proximal End:</b> Proposed	<b>Proximal End:</b> Current PTFE	Different

Characteristic	Subject Device Volo 14 Guidewire (K220398)	Predicate Volo 14 Guidewire (K181828)	Comparison
	PTFE		
<b>Radiopaque Marker</b>	1 radiopaque marker at distal tip	1 radiopaque marker at distal tip	Same
<b>Centering Coil</b>	1 centering coil	1 centering coil	Same
<b>Shaping Mandrel (Accessory)</b>	Provided with each guidewire	Provided with each guidewire	Same
<b>Guidewire Introducer (Accessory)</b>	Provided with each guidewire	Provided with each guidewire	Same
<b>Torque Device (Accessory)</b>	Provided with each guidewire	Provided with each guidewire	Same
<b>Sterilization Method</b>	100% EO	100% EO	Same
<b>Shelf Life</b>	4 month	3 year	Different

**Table 6. Zoom Wire 14 Guidewire Technological Characteristics Comparison**

Characteristic	Subject Device Zoom Wire 14 Guidewire (K220398)	Predicate Zoom 14 Guidewire (K201760)	Comparison
<b>Anatomical Location</b>	Neuro and peripheral vasculature	Neuro and peripheral vasculature	Same
<b>Dimensions</b>	<i>Max O.D.:</i> 0.014" (0.36 mm) <i>Length:</i> 200 cm, 300 cm	<i>Max O.D.:</i> 0.014" (0.36 mm) <i>Length:</i> 200 cm, 300 cm	Same
<b>Core Wire</b>	Stainless Steel	Stainless Steel	Same
<b>Distal Tip</b>	Shapeable <i>Length:</i> 35 cm <i>Material:</i> Nitinol	Shapeable <i>Length:</i> 35 cm <i>Material:</i> Nitinol	Same
<b>Stiffness Profiles</b>	Support, extra support	Support, extra support	Same
<b>Coatings</b>	<i>Distal End:</i> Hydrophilic	<i>Distal End:</i> Hydrophilic	Same

Characteristic	Subject Device Zoom Wire 14 Guidewire (K220398)	Predicate Zoom 14 Guidewire (K201760)	Comparison
	<i>Proximal End:</i> Proposed PTFE	<i>Proximal End:</i> Current PTFE	Different
<b>Radiopaque Marker</b>	Radiopaque marker at distal tip	Radiopaque marker at distal tip	Same
<b>Centering Coil</b>	1 centering coil	1 centering coil	Same
<b>Bushing</b>	None	None	Same
<b>Shaping Mandrel (Accessory)</b>	Provided with each guidewire	NA	Different
<b>Guidewire Introducer (Accessory)</b>	Provided with each guidewire	Provided with each guidewire	Same
<b>Torque Device (Accessory)</b>	Provided with each guidewire	Provided with each guidewire	Same
<b>Sterilization Method</b>	100% EO	100% EO	Same
<b>Shelf Life</b>	4 month	3 year	Different

The subject devices have a different PTFE coating on the proximal end of the guidewire. This difference does not raise new questions of safety and effectiveness, nor does it result in new risks for the subject devices. Testing and evaluation (see below) of the subject devices has been performed with regards to this characteristic and demonstrated the safety and effectiveness of the subject devices.

## **NON-CLINICAL PERFORMANCE TESTS**

### **Biocompatibility**

A biological risk assessment was performed in accordance with recommendations in the ISO 10993 series and ISO 14971:2019 and concluded that the alternative PTFE coating does not impact biocompatibility of the subject devices. The subject devices are considered externally communicating devices with circulating blood contact for a limited duration ( $\leq 24$  hours) and the following tests were performed:

**Table 7. Summary of Biocompatibility Testing**

Test	Test Method Summary	Conclusion
Cytotoxicity	MEM elution cell culture observed for cytotoxic reactivity.	Pass: Non-cytotoxic.
Pyrogenicity	Study animals were observed for individual temperature rise.	Pass: Non-pyrogenic.

Test	Test Method Summary	Conclusion
Sensitization	Study animals with subject device were observed for dermal sensitization.	Pass: Non-sensitizing.
Irritation	Study animals with subject device were observed for dermal reaction.	Pass: Non-irritant.
Acute Systemic Toxicity	Study animals with the subject device were observed for abnormal clinical signs indicative of toxicity.	Pass: No evidence of acute systemic toxicity.
Hemocompatibility	The difference between the hemolytic indexes of the subject device and the negative control was evaluated (direct contact and extract).	Pass: Non-hemolytic.
Complement Activation of SC5b-9	Comparison of the subject device SC5b-9 value to the predicate device for all exposure times was performed.	Pass: The test article complement activation was similar to the comparator device.
Partial Thromboplastin Time	The clotting time was observed for both the subject device and the predicate.	Pass: The test article clotting time was similar to the comparator device.
In Vitro Thrombogenicity	Device is placed in an in vitro blood loop for three runs. The thrombus score for the subject and predicate device is observed.	Pass: Thromboresistant.
Latex Detection	ELISA Inhibition Assay used for the quantitation of extractable latex proteins.	Pass: Latex was not detected.

### Sterilization

The existing validated sterilization cycle uses 100% EO to achieve a sterilization assurance level (SAL) of  $10^{-6}$ , and testing for EO and ethylene chlorohydrin (ECH) residuals and bacterial endotoxin levels were performed.

### Bench Performance Testing

Following review of the risk assessments conducted in accordance with ISO 14971:2012, performance testing was performed on the subject devices. Additional performance tests to evaluate continued compliance with ISO 11070:2014, *Sterile single-use intravascular introducers, dilators and guidewires*, and the FDA guidance document, *Coronary, Peripheral and Neurovascular Guidewires – Performance Tests and Recommended Labeling* (2019), were also performed. Table 8 summarizes these tests and their results below.

**Table 8. Summary of Bench Performance Tests**

Test	Test Method Summary	Results
Visual Inspection and Dimensional Verification	Test per ISO 11070	Acceptance criteria met

Test	Test Method Summary	Results
Coating Integrity Assessment	Test per ISO 11070 and FDA guidance document “ <i>Coronary, Peripheral and Neurovascular Guidewires – Performance Tests and Recommended Labeling</i> ” (2019)	Acceptance criteria met
Corrosion Resistance	Test per ISO 11070	Acceptance criteria met
Agent Compatibility	Test per ISO 11070	Acceptance criteria met
Simulated Use	Anatomical model designed to simulate the tortuous anatomy of the neurovasculature used for simulated use testing.	Acceptance criteria met
Particulate	Particulate measured and counted after use in a simulated pathway model.	Acceptance criteria met

**Animal Testing**

No animal testing was deemed necessary to support the substantial equivalence of the subject devices.

**Clinical Testing**

No clinical testing was deemed necessary to support the substantial equivalence of the subject devices.

**CONCLUSION**

The Aristotle 14 Guidewire, Aristotle 18 Guidewire, Aristotle 24 Guidewire, Volo 14 Guidewire, and Zoom Wire 14 Guidewire have the same intended use and indications for use statement as their respective predicate device. The identified technological difference does not raise new questions of safety or effectiveness regarding the use of the subject devices. Risk evaluation along with testing, bench and biological, was completed for the subject devices. The testing and risk evaluation demonstrate that the subject devices are substantially equivalent to their respective predicate device.